



HDRN Canada

Pragmatic Trials Training Program

ICES Research Forum 2023 (May 11, 2023)

Taylor McLinden, PhD

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Adjunct Research Professor, Western University (Coordinating Centre)



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- What is **HDRN Canada**?
- What is the **Pragmatic Trials Training Program**?
 - **Objectives of the program**
 - **Trainee streams, competencies, teaching modalities**
- **Joint Q&A: Amit, Scott, Kristin, Taylor**

WORKSHOP #2

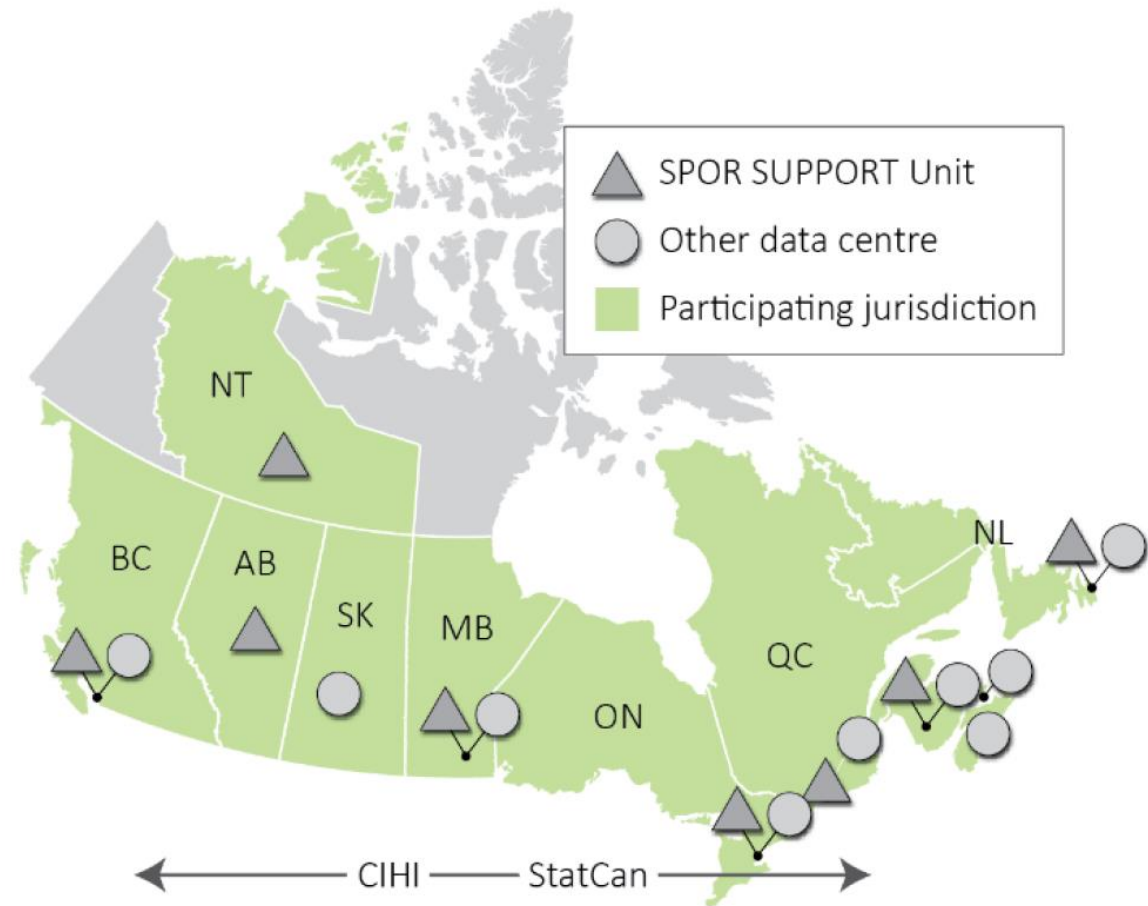
The HDRN Canada Pragmatic Trials Training Program: Building Capacity for Multi-Jurisdictional Research

Pragmatic clinical trials that leverage routinely collected health data can yield valid and generalizable results faster than traditional trials and at a fraction of the cost. However, there is limited capacity to carry out these real-world trials across Canada. In this workshop, we will provide an overview of our newly funded HDRN Canada Pragmatic Trials Training Program and discuss worked examples of pragmatic trials embedded in routine care.





- HDRN Canada: pan-Canadian network**



- Working together to help researchers complete multi-jurisdictional studies using routinely collected health data

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Funding Opportunity Details

Funding Organization	Canadian Institutes of Health Research
Program Name	Training Grant : Clinical Trials Training Platforms ARCHIVED
Program Launch	2022-05-16 (May 16, 2022)

- **CIHR's Clinical Trials Fund:** May 2022

(1) Pan-Canadian trials consortium

(2) **Training platforms**

(3) Clinical trials

Background

The [2021 Federal Budget](#) announced funding for **CIHR's Clinical Trials Fund (CTF)**, an integral component of Canada's [Biomanufacturing and Life Sciences Strategy \(BLSS\)](#). In support of this, the CTF will provide funding through three specific vehicles: platforms with the development of a pan-Canadian Clinical Trials Consortium; people with the funding of **training platforms**; and, projects through the funding of a broad spectrum of clinical trial initiatives.



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<https://www.canada.ca/en/institutes-health-research/news/2023/01/government-of-canada-announces-new-clinical-trials-consortium-training-platforms-and-research-projects-to-improve-the-health-of-canadians.html>

Canada.ca

Government of Canada announces new clinical trials consortium, training platforms, and research projects to improve the health of Canadians

From: [Canadian Institutes of Health Research](#)

News release

January 19, 2023—Hamilton, Ontario—Canadian Institutes of Health Research

Government of Canada / Gouvernement du Canada

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<https://www.canada.ca/en/institutes-health-research/news/2023/01/reinforcing-canadas-clinical-trials-infrastructure-training-and-research.html>

Canada.ca

Reinforcing Canada’s clinical trials infrastructure, training, and research

From: [Canadian Institutes of Health Research](#)

Backgrounder

Clinical trials are an essential part of the healthcare sector and a crucial component of medical research and innovation. Clinical trials allow researchers to assess if new drugs, treatments, and therapies are safe and effective for the population. Announced in Spring 2022, the [Clinical Trials Fund](#) earmarked \$250M across three funding streams to grow and strengthen Canada’s clinical trials infrastructure, training, and research through 2025.

The CTF was [launched](#) in spring 2022 and successful applications were funded through three CTF funding streams:

- Pan-Canadian Clinical Trials Consortium: The Accelerating Clinical Trials Consortium will bring together a team of 232 researchers across the country to support and expand clinical trials networks to improve collaboration, efficiency, knowledge sharing, and quality of clinical trials in Canada.
- Clinical Trials Training Platforms: Seven different training platforms will train the next generation of clinical scientists and researchers to conduct high quality clinical trials
- Clinical Trials Projects: Twenty-two individual clinical trials projects will create the evidence needed to develop new drugs and treatments



- **Clinical Trials Fund:**

- (1) Pan-Canadian trials consortium, (2) **Training platforms**, (3) Clinical trials

Clinical Trials Training Platforms		
1.	The Canadian Behavioural Trials and Interventions Training Platform	Dr. Simon Bacon (Concordia University) \$1,776,068
2.	Canadian Consortium of Clinical Trial Training (CANTRAIN) platform: enhancing career preparedness in RCT research targeting different audiences across the continuum	Dr. Jean Bourbeau (Research Institute of the McGill U Health Centre) \$11,317,324
3.	Canadian Training Platform for Trials Leveraging Existing Networks (CAN-TAP-TALENT)	Dr. Angela Cheung (University Health Network) \$4,314,242
4.	STROKECOG Platform: Innovative Clinical Trials Training Initiatives for STROKE and COGnition	Dr. Jodi D. Edwards (University of Ottawa Heart Institute) \$2,911,416
5.	A Training Platform in Pragmatic Registry-Based Trials: Connecting Canada's Health, Data, and Biomanufacturing Sectors	Dr. Amit Garg (University of Western Ontario) \$3,479,320
6.	Increasing capacity for Maternal and PAediatric Clinical Trials (IMPACT) in Canada	Dr. Lauren Kelly (University of Manitoba) \$4,907,350
7.	Canadian Network for Statistical Training in Trials (CANSTAT)	Dr. Sameer Parpia (McMaster University) \$2,542,144



Nominated Principal Applicant:

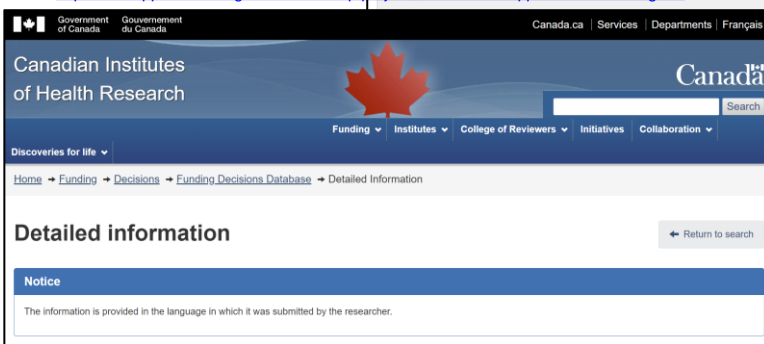
Dr. Amit Garg



https://webapps.cihr-irsc.gc.ca/decisions/p/project_details.html?applId=466263&lang=en

Project title:	A Training Platform in Pragmatic Registry-Based Trials: Connecting Canada's Health, Data, and Biomanufacturing Sectors
Principal investigator(s):	Garg, Amit; Basile, Erika; Bhatia, Rajan S; Clemens, Kristin K; Dixon, Stephanie N; Ethier, Jean-Francois; Fowler, Robert A; Gagnier, Joel J; Garrison, Scott R; Grimshaw, Jeremy M; Hohl, Corinne M; Ivers, Noah M; Jairath, Vipul; James, Matthew T; Jerath, Angela; Katz, Alan; Krzyzanowska, Monika K; Leblanc, Annie; Lee, Douglas S; Mcalister, Finlay A; McGrail, Kimberlyn M; McIntyre, Lauralyn A; Mittmann, Nicole; Naylor, Kyla; Presseau, Justin; Schull, Michael J; Sontrop, Jessica M; Spence, Jessica; Swartz, Richard; Taljaard, Monica; Tangri, Navdeep; Udell, Jacob A; Weijer, Charles E; Zwarenstein, Merrick F
Co-investigator(s):	Barrett, Brendan J; Cohen, Eyal; Cowan, Andrea; Devereaux, Philip J; Fergusson, Dean A; Freier, Amy J; Gershon, Andrea S; Gill, Peter J; Golchi, Shirin; Goldstein, Cory E; Greiver, Michelle; Hebert, Paul C; Hemming, Karla; Hill, Michael D; Kimmelman, Jonathan; Kraut, Roni; Kurdyak, Paul A; Lamontagne, Francois; Lazo-Langner, Alejandro; Li, Fan; Liu, Kuan; Marlin, Susan; Menon, Bijoy K; Moe, Jessica; Ouyang, Yongdong; Parpia, Sameer; Richer, Lawrence P; Roshanov, Pavel; Sajobi, Tolulope T; Sarma, Sisira K; Schorr, Melissa; Street, Catherine A; Tennankore, Karthik K; Thabane, Lehana; Tricco, Andrea C; Wald, Ron; Winquist, Brandace D; Yada, Nicole; Young, Ann
	N/A
	University of Western Ontario
	University of Western Ontario
	Nephrology
	Training Grant: Clinical Trials Training Platforms
	202207
Assigned peer review committee:	Clinical Trials Training Platforms (CTTP)

Many co-applicants
& collaborators
not listed here





- **Pragmatic trials:** combine clinical trial design elements (i.e., randomization) & routinely collected health data

HDRN Canada Pragmatic Trials Training Program

- Pan-Canadian CIHR-funded training program
- Embedded within HDRN Canada
- Coordinated by Schulich School of Medicine & Dentistry, Western University (London, ON)



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Jan

HDRN Canada Pragmatic Trials Training Program focuses on real world data to improve health systems

A new training program, coordinated by the Schulich School of Medicine & Dentistry at Western University, will help researchers use real world data in trials to generate real world evidence and improve health care services and policy.

The **HDRN Canada Pragmatic Trials Training Program** will launch this year, with **\$3.4 million in funding from the Canadian Institutes for Health Research**. Led by **Dr. Amit Garg**, Associate Dean of Clinical Research and a world-renowned clinician-scientist with the Schulich School of Medicine & Dentistry, the program will coach researchers through the complex process of conducting pragmatic clinical trials.

"Clinical trials advance medical care, reduce the costs and burdens of illness on society, and improve health and quality of life for patients with a broad range of health conditions," said Garg, a professor of Medicine, Epidemiology and Biostatistics at Schulich Medicine and a nephrologist at London Health Sciences Centre. But barriers to these kinds of trials exist, he continued, "especially when they want to use real world, routinely-collected data as part of them."

Pragmatic clinical trials are designed to improve practice and policy and unlike most traditional randomized clinical trials, they take place in everyday health care settings, such as community clinics. Embedded within routine health care, pragmatic trials are analyzed using existing real-world data sources and often include patients typically excluded from traditional trials. Pragmatic trials are important because they lead to findings that accurately reflect the impact of simple interventions, which enables health care providers and organizations to gain practical evidence that they can leverage to improve health outcomes.

"Done well, pragmatic trials are faster than traditional trials and can be conducted at a fraction of the cost. Yet few Canadian researchers have the training and experience to conduct them," explained Garg. "The HDRN Canada Pragmatic Trials Training Program will allow us to mobilize Canada's tremendous unrealized resources and provide learners with the skills needed to conduct high-quality pragmatic trials, helping a new generation conduct better, faster, cheaper and more efficient clinical trials."

Kim McGrail, Scientific Director and CEO of HDRN Canada, said the new program will help train researchers to more effectively harness health data. "We are very excited to offer this training program through HDRN Canada under Dr. Garg's leadership," she said. "The use of real world, routinely-collected data for trials has the potential to provide timely and important evidence for health care system improvement." Dr. McGrail added that the program's focus on principles of inclusion, diversity, equity and accessibility will help ensure that pragmatic trials reflect - and therefore benefit - all people in Canada.

To learn more about the training and clinical trial supports that can be provided through the HDRN Canada Pragmatic Trials Training Program, [sign up for our newsletter](#) and get the latest updates.

www.hdrn.ca/en/news/hdrn-canada-pragmatic-trials-training-program-focuses-real-world-data-improve-health-systems

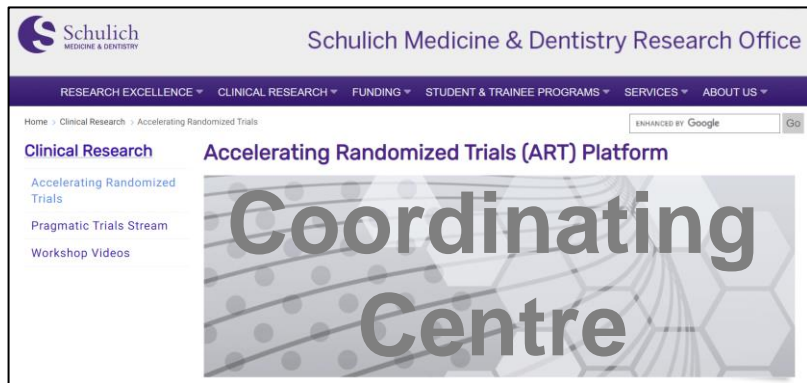


- Pragmatic Trials Training Program:



Réseau de recherche sur les données de santé du Canada
Health Data Research Network Canada

<https://www.hdrn.ca>



https://www.schulich.uwo.ca/research/clinical_research/accelerating_randomized_trials.html



<https://www.act-aec.ca>

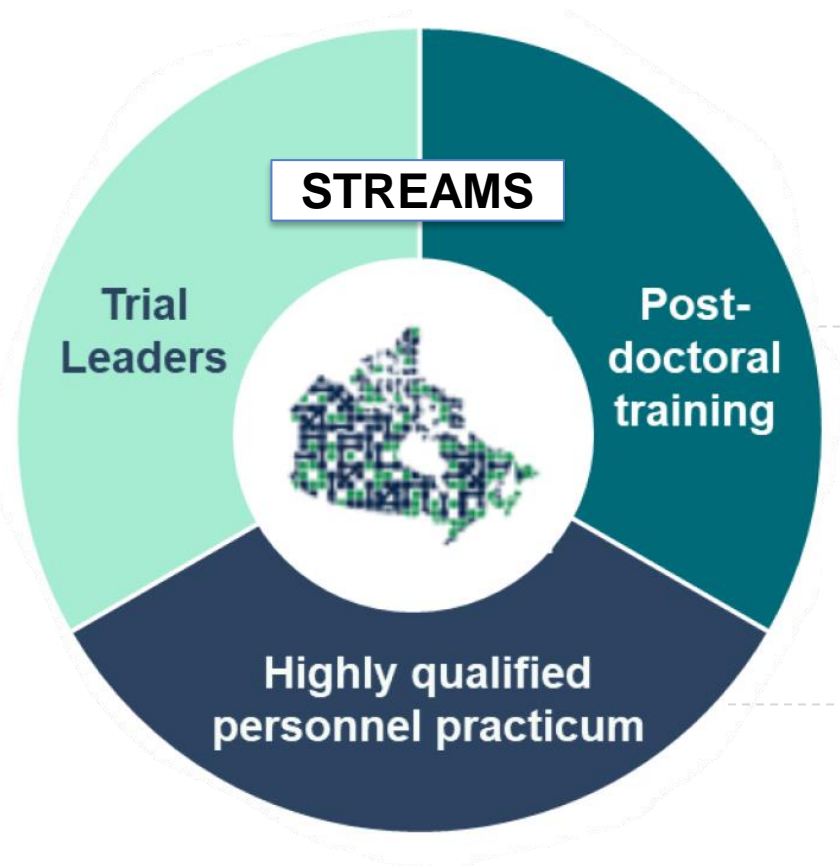




- **Objectives:**

- **1.** Develop & deliver a pan-Canadian **training program** on conducting **pragmatic clinical trials** that are embedded in routine care & use existing data sources
 - **Existing routinely collected health data:** e.g., administrative health data, clinical registries, electronic medical records (EMR) → **in multiple jurisdictions**
- **2.** Support the goals of CIHR's Clinical Trials Fund by **partnering** with the Accelerating Clinical Trials (ACT) Canada Consortium & other trials training programs





- **1. Trial leaders**

- Faculty mentors focused on developing a pragmatic **trial protocol**
- Modeled after ICES Faculty Scholars Program
 - \$: Funding for protocol development support

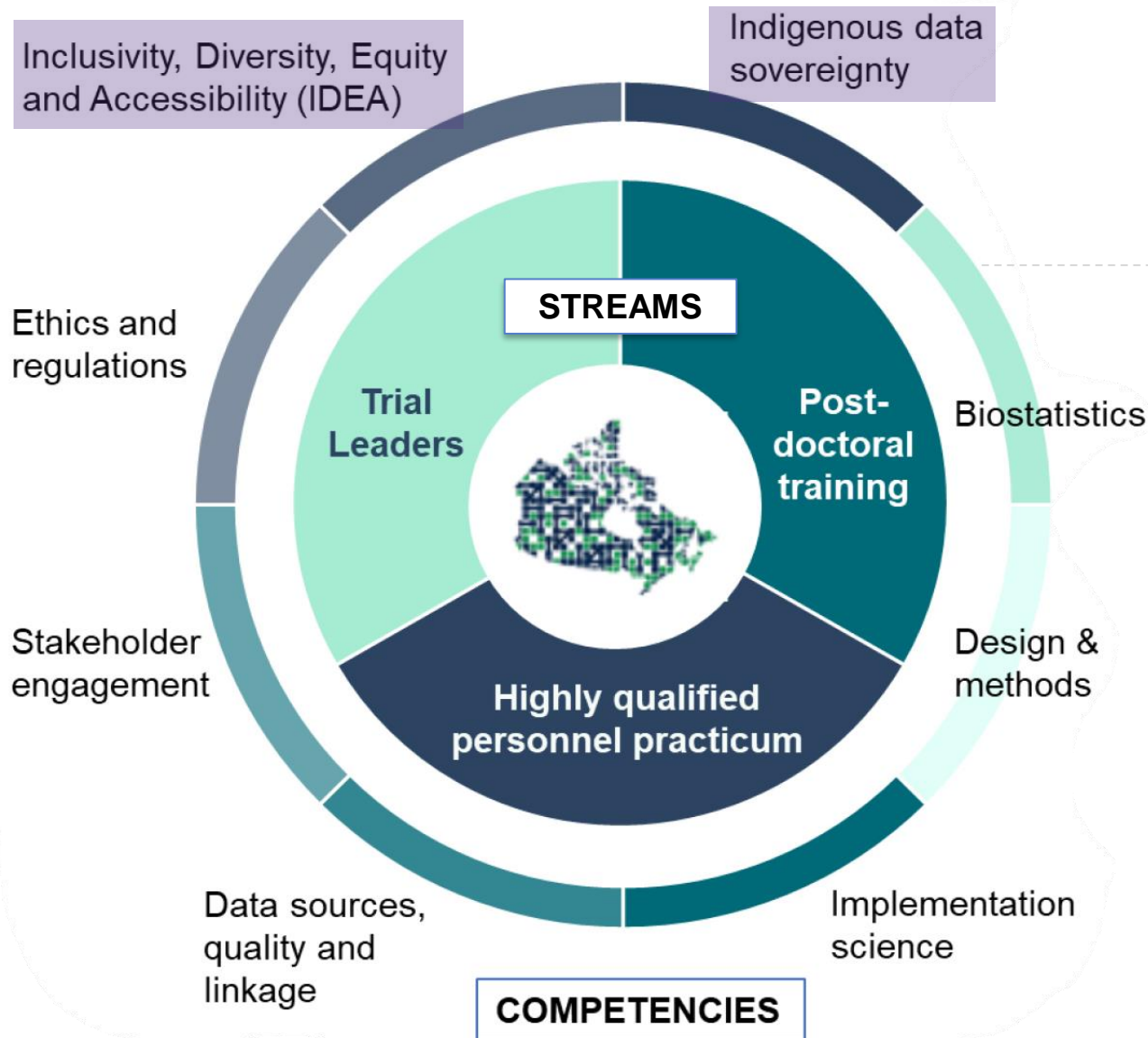


- **2. Postdoctoral fellows**

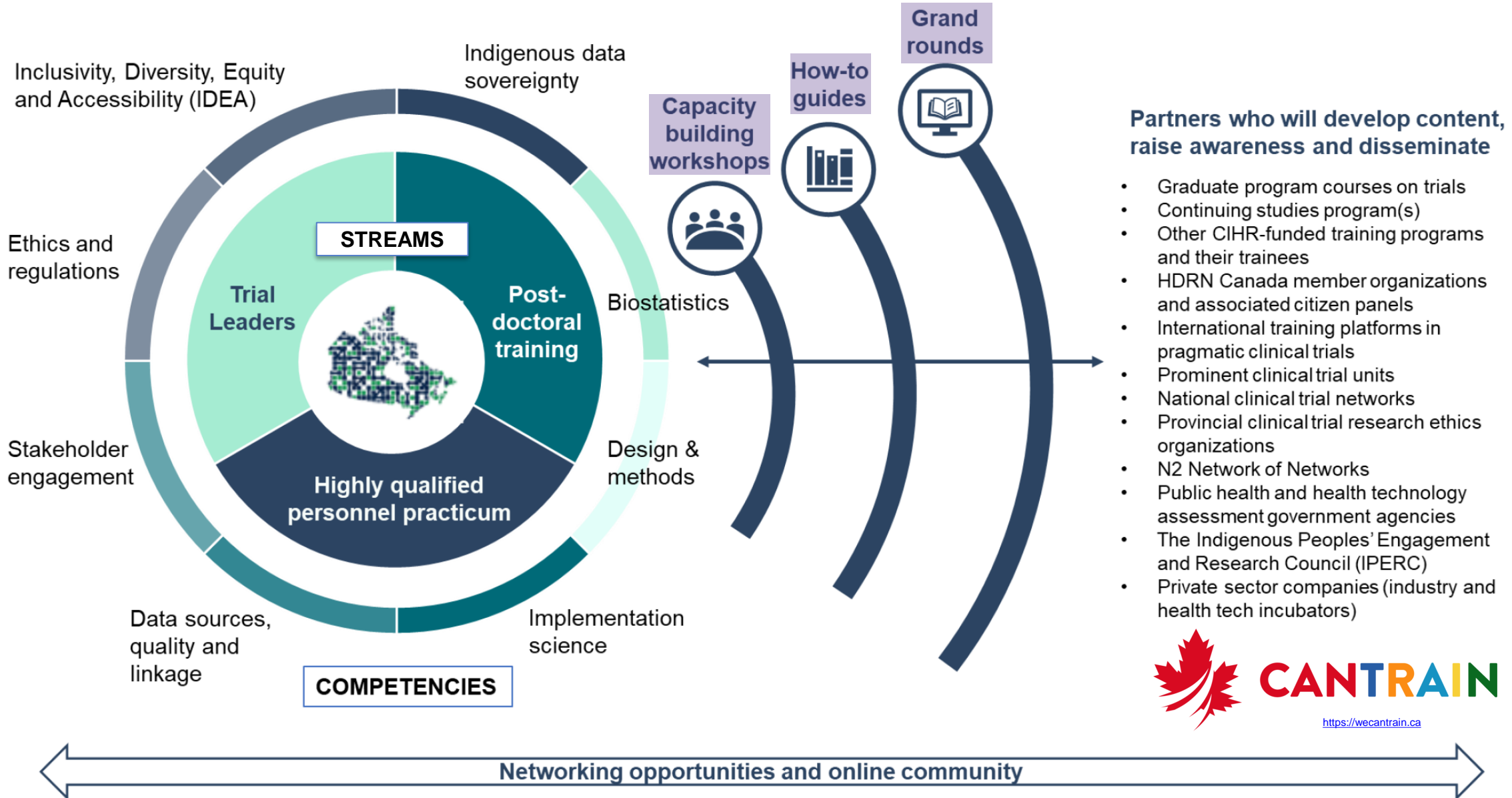
- **Trainees** paired with faculty mentors
- Contributions to the program as educators as well
 - \$: Partial salary support for 2 years

- **3. Highly qualified personnel (HQP)**

- Public & private sector personnel wanting to upskill in pragmatic trials domain
 - \$: Funding for release time for public sector HQP



- **IDEA, Indigenous rights & data sovereignty:** dedicated full-time staff (e.g., Cultural Competency Training Coordinator), partnerships with other pan-Canadian organizations with concentrated expertise
- **Ethics:** e.g., altered patient consent for interventions being tested within routine care
- **Engagement:** e.g., patient partners, healthcare workers (particularly important for trials embedded in routine care)
- **Data sources, quality, & linkage:** e.g., complexities of administrative health data & multi-jurisdictional analyses
- **Design, methods, biostatistics:** e.g., cluster randomization, power & sample size calculations, stepped wedge designs





- **How can I learn more & stay up-to-date?**

- **Web:** Google “HDRN pragmatic” & “Western pragmatic”

- www.hdrn.ca/en/grant-funded-projects/pttp
- www.schulich.uwo.ca/research/student_trainee_programs/pragmatic_trials_training_program.html

- **Social media:**

- www.twitter.com/HDRN_RRDS & www.linkedin.com/company/HDRNRRDS
- www.twitter.com/AmitXGarg
- www.twitter.com/TaylorMcLinden

- : taylor.mclinden@ices.on.ca (to be added to mailing list)





Amit Garg

Senior Scientist and ICES Kidney, Dialysis & Transplantation Program Lead

Dr. Amit Garg has held an appointment with ICES since 2006. He is a nephrologist at the London Health Sciences Centre, where he provides care and conducts research to improve health outcomes for patients with kidney disease including those receiving dialysis or a kidney transplant. He enjoys working with colleagues and trainees in a multi-disciplinary team-based environment to generate and translate new knowledge for better health. Dr. Garg currently serves as Ontario provincial lead for the ICES Kidney, Dialysis, and Transplantation (KDT) Program. He is also the former Site Director of ICES Western.



Scott Garrison

Professor, Dept of Family Medicine, University of Alberta and Director, Pragmatic Trials Collaborative

Scott is a practicing Canadian family physician with a Ph.D. in Experimental Medicine, and a research interest in clinical trials. He leads a practice-based research network known as the Pragmatic Trials Collaborative (www.PragmaticTrials.ca) through which he and his colleagues are conducting 4 large community-based pragmatic trials. One of these, the BedMed trial, has recruited in 5 Canadian provinces and enrolled over 3,000 participants. Scott will describe BedMed, and some of the hurdles that need to be overcome to facilitate multijurisdictional trials in Canada.



Kristin Clemens

Site Director, ICES Western

Kristin Clemens MD MSc is an Assistant Professor of Medicine and Epidemiology and Biostatistics at Western University, an endocrinologist and Medical Director of the Osteoporosis and Metabolic Bone Disease Program at St. Joseph's Health Care London, an Adjunct Scientist at Lawson Health Research Institute, and the new Site Director of ICES Western. As a general endocrinologist, Dr. Clemens cares for patients with multimorbid endocrine disease with a special interest in the care of patients with diabetes, osteoporosis and kidney disease. She conducts research using mixed methods, focused upon improving the clinical care and outcomes of patients with endocrine and kidney disease. Her research has been funded by organizations including CIHR, Diabetes Canada and the Kidney Foundation of Canada.



Taylor McLinden

Manager, HDRN Canada Pragmatic Trials Training Program

Taylor McLinden, Ph.D., is the Manager of the HDRN Canada Pragmatic Trials Training Program (coordinated by the Schulich School of Medicine and Dentistry, Western University). He holds positions at ICES Western, HDRN Canada, and the London Health Sciences Centre. He also has an appointment as an Adjunct Research Professor in the Department of Epidemiology and Biostatistics at Western University. Previously, he was an Epidemiologist and Scientific Officer at the British Columbia Centre for Excellence in HIV/AIDS. Prior to a postdoctoral fellowship in Vancouver, Taylor completed a Ph.D. in Epidemiology at McGill University. He also earned a MSc (Epidemiology) from the University of Guelph and an Honours BSc (Biomedical Sciences) from Brock University.

9:30 – 10:55 AM

1. What are pragmatic trials?

2. Example trial:



3. Example trial:



4. Example trial:



5. Pragmatic Trials Training Program

